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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/764,617      | 01/16/2001  | Gene A. Bornzin      | A01P1002            | 7875             |

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EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/764,617

Applicant(s)

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 7, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Snell (US 5722999). Snell discloses a system and method for storing and displaying historical medical data measured by an implant medical device. Data is acquired, integrated, stored and displayed for a medical practitioner to assist in decision-making regarding the device settings (c 6, ll 15-26). The system includes and implantable medical device and a programmer with telemetry capability (c 4, ll 1-7). Data includes ECG and IECG images, and waveforms can be annotated with markers (c 4, ll 8-16 and c 11, ll 23-30). The user input device (62) enables the selection of options (c 8, ll 60-65). The printer is used to print text and graphical data (c 9, ll 3-4; c 10, ll 41-54 and c 13, ll 16-27). Tests such as the capture threshold tests can be preformed automatically or on demand, and the diagnostic equipment can be internal (IECG) or external (ECG) (c 13, l 53 – c 14, l 3).

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 2, 3, 8-12, 14, 15, and 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell (US 5722999) in view of Olive et al. (US 5855594). As discussed in paragraph 1 of this action, Snell discloses the claimed invention except for:

- specifying the atria or ventricle is selected (claim 2),
- providing and selecting from a plurality of unique means for automatic capture verification (claim 3),
- defining and recording the amplitude and duration characteristics for each pulse (claim 8, 19),
- marking to represent capture and absence of capture (claim 9, 15, 20, 22 ),
- assessing the threshold value and adding a safety margin, the recommendation being displayed (claim 10), and
- providing an additional representation of the threshold assessment (claim 12, 21).

Olive et al. disclose a self calibrating system for capture verification in pacing devices and teach that it is known to:

- specify the atria or ventricle is selected (claim 2) (c 5, ll 49-52),

- provide and select from a plurality of unique means for automatic capture verification (claim 3) (c 2, ll 24-32 and c 3, l 45 – c 4, l 43),
- define and record the amplitude and duration characteristics for each pulse (claim 8, 19) (c 3, ll 9-30),
- mark to represent capture and absence of capture (claim 9, 15, 20, 22 ) (the generated response value read as an indication of capture or lack of capture; c 6, ll 35-54),
- assess the threshold value and adding a safety margin, the recommendation being displayed (claim 10) (c 3, ll 27-33), and
- provide an additional representation of the threshold assessment (claim 12, 21) (figures 6 and 7; c 8, ll 50-55; c 9, ll 5-7) .

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method for storing and displaying historical medical data measured by an implant medical device as taught by Snell, with the operational details of the capture verification test as taught by Olive et al. to define the steps and features required for accurate capture verification so changes in the patient's stimulation threshold are accurately tracked allowing for more effective adjustments in the level of stimulation pulses.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FPO*  
*6/26/02*

  
JEFFREY R. JASTRZAB  
PRIMARY EXAMINER

*3762*  
*6/26/02*